

REMARKS

These remarks are filed in response to the Examiner's Report of November 6, 2007, a response to which is due by February 6, 2008. Accordingly, the Applicants respectfully submit that no extension of time fees fall due in connection with the filing of this paper. If the Applicants are mistaken, the Commissioner is hereby authorized to deduct any necessary fees from our Deposit Account No. 13-2400.

Election/Restrictions

Applicant thanks the Examiner for rejoining claims 37-47 to the instant application.

35 USC 112

Applicant thanks the Examiner for withdrawing the rejection of claim 48 under 35 USC 112, first paragraph.

Applicant thanks the Examiner for withdrawing the rejection of claim 48 under 35 USC 112, second paragraph.

The Examiner has rejected claims 37-38 under 35 USC 112, first paragraph, stating that, **while the specification is enabling for an opioid formulation comprising either (1) fentanyl and liposomally encapsulated fentanyl or (2) the combination of (a) remifentanyl, alfentanil, sufentanil, or fentanyl and (b) methadone, wherein said formulation induces analgesia before the onset of side effects and or/toxicity**, the specification is not enabling for a method wherein the formulation comprises any rapid onset opioid.

Though Applicant disagrees with the latter, solely in an effort to expedite prosecution, Applicant has amended claim 37 to include the former limitation (i.e. that the opioid formulation comprises either (1) fentanyl and liposomally encapsulated fentanyl or (2) the combination of (a) remifentanyl, alfentanil, sufentanil, or fentanyl and (b) methadone, wherein said formulation induces analgesia before the onset of side effects and or/toxicity). Applicant submits that this limitation amply addresses the Examiner's rejection, and places the claim (and claims dependent thereupon) in a position acceptable for allowance.

The Examiner has rejected claims 38-47 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner has objected to the "means + function" claim language, specifically the (i) means for forming the formulation into particles (claims 38-39); (ii) means for dispensing said formulation (claims 38-39 and 44); and (iii) delivery rate controlling means for limiting the rate (claim 40).

Applicant has amended claims 38, 39, and 44 to remove the "means + function" language. Applicant has cancelled claim 40. Thus, Applicant respectfully submits these claim rejections are now moot.

The Examiner has rejected claim 28 as vague and indefinite, because said claim depends from a cancelled claim. Applicant notes that claim 28 has been cancelled, rendering this rejection moot.

The Examiner has rejected claims 39 and 44 as unclear, stating that it is unclear what is meant by the "other types of opioid". Applicant believes that amendments to claims 39 and 44 limiting the opioids claimed to a variety of

different types of opioid, (i.e. fentanyl, remifentanyl, etc.) render this rejection moot.

The Examiner has rejected claims 46-47 as vague and indefinite, because said claims depend from a cancelled claim. Applicant has cancelled claims 46 and 47, rendering this rejection moot.

The Examiner has rejected claims 46-47 as a claimed recitation of use, without any steps involved in the method/process. Applicant has cancelled claims 46-47, rendering this rejection moot.

The Examiner has rejected the remainder of the claims (claims 40-43 and 45) as being dependent on an indefinite claim. Applicant has cancelled claim 40, rendering this rejection, with respect to that claim, moot. Applicant submits that the claim amendments to claims 39 and 44 render this rejection moot with respect to claims 41-43 and 45.

35 USC 101

The Examiner has rejected claims 46-47 for a claimed recitation of a use/process, without setting forth any steps involved in the process. Applicant has cancelled claims 46-47, rendering this rejection moot.

35 USC 103

Applicant thanks the Examiner for his withdrawal of the rejection of claims 29-36 and 48 under 35 USC 103(a).

Double Patenting

The Examiner has provisionally rejected claims 29 and 48 as claiming the same invention as that of claims 10 and 56 of copending Application number

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10/927,145. The Examiner has also rejected claims 29-30, 33-37, 39, 41 and 44-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 13-14, 28-33 and 46 of copending Application number 10/927,145. In response, Applicant files concurrently a Terminal Disclaimer, rendering this rejection moot.

Conclusion

It is respectfully submitted that the present amendments and remarks herein are a complete response to all outstanding issues. Favorable consideration is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully Submitted,
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